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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,993	04/04/2002	Pierre Etienne Chabrier de Lassauniere	427.057	5815

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EXAMINER	
ANDERSON, REBECCA L	
ART UNIT	PAPER NUMBER
1626	
MAIL DATE	DELIVERY MODE
08/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/089,993	CHABRIER DE LASSAUNIERE ET AL.	
	Examiner	Art Unit	
	Rebecca L. Anderson	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *36-38* is/are pending in the application.

4a) Of the above claim(s) *38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *36 and 37* is/are rejected.

7)☒ Claim(s) *36* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 36-38 are currently pending in the instant application. Claims 36 and 37 are rejected, claim 36 is objected and claim 38 is withdrawn from consideration as being for non-elected subject matter.

Response to Amendment and Arguments

Applicants' amendment to the claims has overcome: has overcome the 35 USC 112 2nd paragraph rejection of the claims; has overcome the statutory double patenting rejection of the claims; and has overcome the obvious type double patenting rejection of the claims. The 35 USC 112 1st paragraph rejection for containing new matter is maintained for the pending claims as is the 35 USC 112 1st paragraph rejection of the claims for lacking enablement. Additionally, the objection to the claims as containing non-elected subject matter is maintained as applicants elected invention was Group I wherein Y is O and claim 36, and withdrawn claim 38, have a compound wherein Y is S.

Applicant's arguments filed 12 June 2007 have been fully considered but they are not persuasive. Applicant argues that the specification supports the claimed method of treating Parkinson disease and applicant has submitted four literature references. These arguments are not persuasive. While applicants' specification discusses the treatment of Parkinson disease and the involvement of MAO on pages 1, 2, 6 and 13 and has pharmacological test data on page 171-173, the specification does not provide any pharmaceutical data for the treatment of Parkinson's disease and there is no other guidance or direction present as to how Parkinson's disease can be treated. While applicant has provided four references, it is noted that none of the references are

directed to structurally similar compounds to the claimed invention, i.e. selegiline and rasagiline are not structurally similar compounds to those found in the instant claims. Furthermore, the Stoll reference supports the examiner's argument that animal models of Parkinson's disease may not be totally reflective of the disease as the tested compound worked in rats and hamsters, but not in mice. Additionally, the Guay reference provides that rasagiline has only been shown for early-stage disease and MAO-B inhibitors have a limited role in Parkinson's treatment. Therefore, since it is the state of the art that: in spite of the extensive studies performed on postmortem substantia nigra from Parkinson's disease patients, the aetiology of the disease has not yet been established (Mandel, 730) and despite the success obtained with animal models, clinical neuroprotection is much more difficult to accomplish; that animal models of Parkinson's disease may not be totally reflective of the disease and a single drug may not be adequate to induce neuroprotection (Mandel 730); that major consideration should be given to the optimal time at which to initiate the neuroprotective attempts and it must be aimed at the preclinical stage of the disease of which our ability to identify is currently very limited (page 752); and that the general failure to induce neuroprotection in the clinic versus in the laboratory with currently available drugs suggests that a single drug would not be sufficiently active and/or that the animal models we are employing are not truly representative of the disease state (page 752), the instantly claimed invention is not enabled as the existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic or preventive regimen on its face.

Maintained Claim Objections

Claims 36 is objected to as containing non-elected subject matter. Claims 36 presented drawn solely to the elected invention as identified supra would overcome this objection.

Maintained Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 36 and 37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, 36 has introduced new matter into the claims as the "amount of a compound ..... sufficient to treat Parkinson disease" is not found in the originally filed disclosure. Applicants' amendment has introduced new matter as nowhere in the originally filed disclosure is there mention of what amount of the compound would be sufficient to treat Parkinson disease, nor is there any examples or direction to the treatment of Parkinson's disease with any amount of the formula claimed. The administration dose envisaged for a medicament on page 70, does not provide direction, motivation, or support for the instant claim language. Claims which change the scope relative to the originally filed claims may lack written description, see In re Ruschig, 371 F.2d 990, 154 USPQ 118 (CCPA) 1967) which

supports that the original disclosure of a large genus did not support a later filed claim to a previously unnamed single species. Furthermore, Purdue Pharma L.P. v. Faulding Inc., 230 F.3d 1320, 1326, 56 USPQ2d 1481, 1486 (Fed. Cir.2000) notes that with respect to In re Ruschig, that "Ruschig makes clear that one cannot disclose a forest in the original application, and then later pick a tree out of the forest and say "here is my invention". In order to satisfy the written description requirement, the blaze marks directing the skilled artisan to that tree must be in the originally filed disclosure." The only written description in Applicants' originally filed claims is for a blanket administrative dose and no direction or disclosure of a dose for the treatment of Parkinson's disease is found and therefore fails to have written description and is considered new matter.

Claims 36 and 37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In In re Wands, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

The nature of the invention

The nature of the invention of the claims is the treatment of Parkinson's disease.

The state of the prior art and the predictability or lack thereof in the art

The state of the prior art is that it involves screening in vitro and in vivo to determine which compounds exhibit the desired pharmacological activities (i.e. what compounds can treat which specific disease). There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic or preventive regimen on its face.

The instant claimed invention is highly unpredictable as discussed below:
It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the instant claimed invention is highly unpredictable since one skilled in the art would recognize that in regards to therapeutic effects of disorders, whether or not the disease is effected by inhibiting monoamine oxidases and lipidic peroxidation and modulating activity vis-a`-vis sodium channels would make a difference.

It is the state of the art that in spite of the extensive studies performed on postmortem substantia nigra from Parkinson's disease patients, the aetiology of the disease has not yet been established (Mandel, 730) and despite the success obtained with animal models, clinical neuroprotection is much more difficult to accomplish.

Additionally, animal models of Parkinson's disease may not be totally reflective of the disease and a single drug may not be adequate to induce neuroprotection (Mandel 730). Additionally, major consideration should be given to the optimal time at which to initiate the neuroprotective attempts and it must be aimed at the preclinical stage of the disease of which our ability to identify is currently very limited (page 752). The general failure to induce neuroprotection in the clinic versus in the laboratory with currently available drugs suggests that a single drug would not be sufficiently active and/or that the animal models we are employing are not truly representative of the disease state (page 752).

Hence, in the absence of a showing of correlation between all the disorders claimed as capable of treatment one of skill in the art is unable to fully predict possible results from the administration of the compound of formula (I)3 due to the unpredictability of the role of the inhibiting monoamine oxidases and lipidic peroxidation and modulating activity vis-a`-vis sodium channels, and since the inhibition of excess amounts of glutamate and the treatment of Parkinson's disease does not appear to be adequate with one drug.

The amount of direction or guidance present and the presence or absence of working examples

The only direction and guidance present in the specification is a list of disorders on pages 1, 2 and 69 that applicant considers treatable by inhibiting monoamine oxidases and lipidic peroxidation and modulating activity vis-a`-vis sodium channels and bond reactions on pages 171-174. There is no correlation between inhibiting

monoamine oxidases and lipidic peroxidation and modulating activity vis-a`-vis sodium channels with any disorder let alone Parkinson's disease and the specification does not provide any pharmaceutical data for the treatment of any specific disorder, i.e. the specification is silent and fails to provide guidance as to what diseases are mediated by inhibiting monoamine oxidases and lipidic peroxidation and modulating activity vis-a`-vis sodium channels. There no other guidance or direction present as to what diseases can be treated and there is no guidance as to how these diseases can be treated.

The breadth of the claims

The breadth of the claims is the treatment of Parkinson's disease.

The quantity of experimentation needed

The quantity of experimentation needed is undue experimentation. One of skill in the art would need to determine whether Parkinson's disease would be benefited by the inhibiting monoamine oxidases and lipidic peroxidation and modulating activity vis-a`-vis sodium channels and would furthermore then have to determine if the compound claimed would provide treatment of the disorder.

The level of the skill in the art

The level of skill in the art is high. However, due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by in vitro and in vivo screening to determine which compounds exhibit the desired pharmacological activity and which diseases would benefit from this activity.

Thus, the specification fails to provide sufficient support of the broad use of the compound for the treatment of Parkinson's disease by administering the compound as claimed.

Genentech Inc. v. Novo Nordisk A/S (CA FC) 42 USPQ2d 1001 , states that " a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the Wands factors and In re Fisher (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test whether Parkinson's disease can be treated by the compound encompassed in the instant claims, with no assurance of success.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (571) 272-0696. Mrs. Anderson can normally be reached Monday through Friday from 6:00am until 2:30pm.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rebecca Anderson/
Primary Examiner, AU 1626

20 August 2007

Rebecca Anderson
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